DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 22 1996

Ms. Diana G. Williams
Manager, Government Regulations
Northrup King Company
P. O. Box 959
Minneapolis, MN 55440

Dear Ms. Williams:

This is in regard to Northrup King's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified corn, specifically transformation event Bt 11. According to Northrup King, transformation event Bt 11 corn is modified to express synthetic versions of the modified *CrylA(b)* and *pat* genes, similar to the *CrylA(b)* and *pat* genes isolated from *Bacillus thuringiensis* var. *kurstaki* (Btk) and *Streptomyces viridochromogenes*, respectively. The *CrylA(b)* gene encodes the Btk protein, which is toxic to certain lepidopteran insects upon ingestion. The *pat* gene encodes the phosphinothricin acetyltransferase (PAT) protein, which confers tolerance to the herbicide glufosinate ammonium. For Northrup King's purpose, PAT expression functions as a selectable marker for development of the Bt 11 corn line.

In February of 1995, Northrup King met with FDA to discuss their proposed safety and nutritional assessment of corn containing transformation event Bt 11. As part of bringing Northrup King's consultation regarding this product to closure, Northrup King submitted a summary assessment of corn containing transformation event Bt 11 on October 25, 1995. Additional submissions were received by the Agency on February 28, 1996 and May 14, 1996.

These communications informed FDA of the steps taken by Northrup King to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Northrup King has concluded that corn grain (kernels), fodder, and silage derived from the new variety, are not materially different in composition, safety, and other relevant parameters from corn grain, fodder and silage currently on the market and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0017. This file will be maintained in the Office of Premarket Approval.

Based on the information Northrup King has presented, we have no further questions concerning grain, fodder, and silage from event Bt 11 at this time. However, as you are aware, it is Northrup King's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/S/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247
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